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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Shlomo Ben-Haim

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02/28/2008

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EXAMINER

HOLMES, REX R

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

02/28/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO@WOLFBLOCK.COM

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,748	<b>Applicant(s)</b> BEN-HAIM ET AL.	
	<b>Examiner</b> REX HOLMES	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 10-15, 30, 32-47, 49-53, 55-58 and 72-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 10, 11, 13, 15, 30, 36-38, 40-43, 45-47, 51, 55, 56, 58 and 72-85 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 8, 12, 14, 32-35, 39, 44, 49, 50, 52, 53 and 57 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/20/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/08/07 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 72-85 are rejected under 35 U.S.C. 102(b) as being anticipated by KenKnight (U.S. Pat. 5,797,967).

4. Regarding claims 72-85, KenKnight discloses that pacing bursts are used to control fibrillation (Col. 10, ll. 57-67; Col. 11, ll. 1-11), it is further disclosed that during pacing type stimulation 1-10 V are used (Col. 5, ll. 41-45), it is further discussed that the amperage used is 10mA and the duration of 40 pulses was about 100-140ms (Col. 10, ll. 57-67 & Col. 11, ll. 1-11). Based on the voltages, amperage, the number of shocks and the duration KenKnight discloses a method and apparatus of defibrillating a heart at a rate of 10Hz for at least 100ms (~100-140ms) while supplying total energy that is less

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than 1 joule having an amplitude less than 50mA and a peak power that is less than 10 W. KenKnight further discloses that the method and apparatus comprises a step for or a controller for sensing the activity in the heart and then respond to it by pulsing in bursts (Column 1, Lines 42-45; Column 11, Lines 60-66). KenKnight also discloses the use of fencing signals to inhibit and control activation fronts (Column 11, Lines 12-34).

KenKnight discloses further discloses that the pulses are applied with different parameters to a variety of sites interspersed within the heart (Column 8, Lines 65-67; Figure 8, 14a, 14b, 13). It is also disclosed that the controller is programmed to determine the activation interval after the first shock and then continued application of pulses is computed and applied. It is further disclosed that after each defibrillation pulse the application of the first defibrillation-level shock, a new and longer cycle length is used to control the critical tissue volume. KenKnight also discloses that the pulses occur near the peak of ventricular depolarization, thus causing depolarization (Column 1, Lines 25-27). It is further stated that the selected cardiac tissue may be ventricular or atrial tissue (Column 4, Lines 4-9).

It is noted that local control of the heart along with activation front control described in Column 11, Lines 12-34 describes fencing signals without explicitly calling them fencing signals. It is further noted that atrial depolarization cued to the start of ventricular depolarization causes depolarization of substantially all excitable contractile tissue of the heart.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3, 7, 10-11, 13, 15, 45-47, 51, 55-56, 58, 72-74, 76-77 and 79-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra (U.S. Pat. 5,683,429).

8. Regarding claims 1-3, 7, 10, 45-47, 51, 55, 72-74, 76-77, 79-81 and 83-84, Mehra discloses a system for defibrillating the heart via pacing pulses without the use of defibrillation shocks (Col. 5, ll. 59-64). Mehra discloses that the system senses fibrillation and then applies pulses to the heart and then terminating the stimulation once the fibrillation is terminated (Col. 5, ll. 59-67; Col. 6, ll. 1-3). Mehra further discloses that the specific frequency, pulse amplitude, pulse width, and number of pulses delivered

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are selected by the implanting physician (Col. 12, ll. 8-12). Mehra discloses an example that includes a frequency greater than 10Hz (~20Hz -200 Hz), pulse energy less than 1 joule (~0.05 J), with a burst duration of at least 100 ms (Col. 11, ll. 64-67; Col. 12, ll. 1-21).

9. Regarding claim 11, Mehra discloses that the electrodes are positioned at multiple sites around the heart.

10. Regarding claims 13, 15, 56-57 and 82, Mehra discloses that the pulses are delivered and are sufficient to depolarize the entire atrium (Col. 12, ll. 6-7).

11. Regarding claims 1-3, 7, 10-11, 13, 15, 45-47, 51, 55-56, 72-74, 76-77 and 79-84, Mehra disclose the claimed invention including that the specific frequency, pulse amplitude, pulse width, and number of pulses delivered are selected by the implanting physician except for explicitly stating the peak power and current amplitude values. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the frequencies, amplitudes and power of the pulses of the system as taught by Maher to, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

12. It is noted that the device of Mehra is capable of being configured to sense and start pacing the heart when the heart is in ventricular fibrillation (Col. 12, ll. 51-60).

13. Claims 30, 36-38 and 40-43 rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra in view of Hess et al. (U.S. Pat. 5,713,929 hereinafter "Hess").

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14. Claims 30, 36-38 and 40-43 are rejected under 35 U.S.C. 103 as being unpatentable over Mehra in view of Hess. Mehra teaches a system for defibrillating the atrium of the heart using pacing level stimulation without the use of defibrillation shocks. A person of ordinary skill in the art, upon reading the reference, would also have recognized the desirability of improved methods of improved methods for treating ventricular fibrillation. Hess teaches a method of pacing to prevent atrial fibrillation and further discloses that the methods can be used to treat ventricular fibrillation (Col. 1, ll. 6-13). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to try methods of Mehra for ventricular fibrillation, as a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. In turn, since Mehra discloses a method of pacing the atrium to defibrillate the heart without a defibrillation shock, and the prior discloses a pacing method to treat fibrillation that can be used in either the atrium or the ventricles, it would have been obvious to use the method of Mehra in the ventricles.

***Allowable Subject Matter***

15. Claims 5-6, 8, 12, 14, 32-35, 39, 44, 49-50, 52-53 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./  
Examiner, Art Unit 3762  
/George R Evanisko/  
Primary Examiner, Art Unit 3762